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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,895	03/19/2004	Madhavan Pisharodi	PISA,015	8181
7590	06/05/2007			
Mark Wisner c/o Wisner & Associates Suite 400 1177 West Loop South Houston, TX 77027			EXAMINER PREBILIC, PAUL B	
			ART UNIT 3738	PAPER NUMBER
			MAIL DATE 06/05/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/804,895

Applicant(s)

PISHARODI, MADHAVAN

Examiner

Paul B. Prebilic

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 1 and 3-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2 and 19-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date various.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 16, 2006 has been entered.

Supplemental Amendments

The supplemental replies filed on May 4, 2007 and May 16, 2007 were not entered because supplemental replies are not entered as a matter of right except as provided in 37 CFR 1.111(a)(2)(ii). These amendments did not comply with the requirements of 37 CFR 1.111 (a) (2); see MPEP 714.01(e), last paragraph, that explains that an RCE is not a new application. Amendments filed after the RCE is filed are considered to be supplemental replies that are not entered as a matter if right.

Election/Restrictions

Claims 1 and 3-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention or species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on February 27, 2006.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The new language requiring the width be greater than the height lacks original support where the width is first contacted with the vertebra prior to rotation.

Claim Objections

Claims 2, 20, and 23 are objected to because of the following informalities:

With regard to claim 2, on line 7, it is unclear how a portion of the implant can be biased away from "the implant" as claimed. Rather, a portion of the implant is biased away from "another portion" of the implant. The Examiner suggests making this change to make the claim language clearer.

In claim 2, the preamble is confusing because so many clauses are strung together that it is unclear which two elements are provided with cushioning between them.

On line 6 of claim 2, "the elongate implant" lacks antecedent basis because of the term "elongate."

On line 7 of claim 2, since "the width" is a dimension instead of a structural feature, it is confusing to say that the width is in contact with the adjacent vertebra.

On line 10 of claim 2, since "the height" is a dimension instead of a structural element, it is confusing to say that the width is in contact with adjacent vertebra.

With regard to claim 20, "polyvinylpyrrolidine" is a misspelling for "polyvinylpyrrolidone."

With regard to 23, it is unclear what element(s) are being sealed. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 19, and 24-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Perren et al (US 6,019,793). Perren anticipates the claim language where the inserting step as claimed is met by the inserting step of Perren (see column 3, line 66 to column 4, line 2 and see column 1, line 55 to column 2, line 12), the insert as claimed is one of either the upper plate (1) or lower plate (1), and the biasing step as claimed is done by means (4) of Perren.

With regard to claim 24, the springs as claimed are met by the connecting means (4) of Perren.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 19-21, 24, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ralph et al (US 6,669,731) or Ralph et al (US 5,989,291) in view of Muhanna (US 6,936,070). Ralph ('291) meets the claim language where the inserting step as claimed is disclosed by Ralph '291 on column 5, lines 49-65, the implant is upper plate (102a or 103a), the insert as claimed is the lower plate (102b or 103b), the biasing is done by the Belleville washer (130 or 230) and the step thereof is disclosed on column 2, lines 43-55, and the restraining step as claimed is disclosed by Ralph on column 2, lines 56-65. Alternatively, Ralph ('731) meets the claim language where the implant as claimed is the plate (102b) (see Figure 5), the insert as claimed is the plate (102a), and the biasing is done by the washer (130) (see Figure 5, column 2, line 52 to column 3, line 68, and column 6, lines 31-53) Both Ralph '291 and '731 fail to disclose the step of removing a portion of the intervertebral disk as claimed. However, Muhanna teaches that removal of the intervertebral disk prior to implantation of Ralph ('291) was clearly known to the art; see column 2, lines 9-22. Therefore, it is the Examiner's position that it would have been clearly obvious, if not required for operability, to remove at least a portion of the intervertebral disk in either the Ralph('731) or Ralph ('291) method to make room for the implant that replaces the structure and function of the defective disk.

With regard to claims 20-21, Muhanna teaches that it was known to fill a space around a similar implant with collagen gel, which is a type of hydrogel; see column 7,

lines 3-19. Therefore, it is the Examiner's position that it would have been obvious to an ordinary artisan to fill any space around either of the Ralph implants with collagen gel for the same reasons that Muhanna does the same or to aid in the cushioning effect desired.

With regard to claim 21, collagen gel is considered to be a protein polymer or a collagen matrix to the extent that this language can be given patentable weight.

Claims 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ralph et al ('731), Ralph et al ('291), and Muhanna as applied to claims 19-21, 24 and 26 above, and further in view of Haldimann (US 6,428,576). Ralph ('731) or Ralph ('291) fail to disclose the use of an adhesive in the implantation method to contact the remaining disk or to seal an opening as claimed. However, Haldimann teaches that it was known to use medical grade adhesives to contact the disk and to seal openings; see Figure 1 and column 4, lines 27-48. Therefore, it is the Examiner's position that it would have been obvious to use the medical grade adhesive of Haldimann to contact the disk and to seal any openings in order to prevent migration of the implant or further herniation of the disk or for the same reasons that Haldimann utilizes the same.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but were not persuasive.

The Applicant argues that the claimed invention is patentable over Perren because it is said require complete removal of the disk, but that the present claims require removal of "only a portion of the disk." However, the present claims are not

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limited to removing "only" a portion of the disk, but rather, require removal of at least a portion of the disk since it is open-ended language. In other words, the insertion of "only" before "a portion" would change the scope of the claims such that removal of the entire disk would not meet the claim language.

Conclusion

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Paul Prebilic/
Paul Prebilic
Primary Examiner
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